



PHA 2012.1 (3167/4Z/US)  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of John P. McKearn et al.

Art Unit 1614

Serial No. 09/857,873

Filed October 5, 2001

Confirmation No. 2817

For METHOD OF USING A CYCLOOXYGENASE 2 INHIBITOR AND ONE OR  
MORE ANTINEOPLASTIC AGENTS AS A COMBINATION THERAPY IN THE  
TREATMENT OF NEOPLASIA

Examiner Rebecca Cook

January 21, 2004

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VIRGINIA 22313-1450

SIR:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

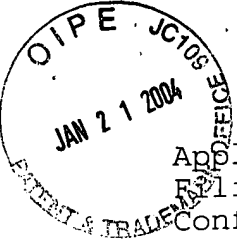
In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit copies of the references listed on the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein.

In preparation of this Supplemental Information Disclosure Statement, Applicants determined that approximately 1,000 references were cited in the application. In an effort to reduce the burden on the Office, each reference was briefly reviewed by an attorney. This review eliminated any reference that was determined to be irrelevant or merely cumulative. If the Office would like a copy of the eliminated references, they can be provided at the Office's request.

01/26/2004 HROCHA1 00000056 191345 09857873

01 FC:1006

100.00 DA



FEE TRANSMITTAL

Application Number 09/857,873  
Filing Date October 5, 2001  
Confirmation No. 2817  
Inventor(s) John P. McKearn et al.  
Attorney Docket Number PHA 2012.1 (3167/4Z/US)  
Examiner Rebecca Cook

Art Unit 1614

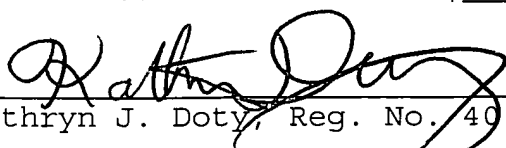
**METHOD OF PAYMENT**

1. ☒ The Commissioner is hereby authorized to charge the indicated fees to Deposit Account No. 19-1345.
- ☐ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 to Deposit Account No. 19-1345.
- ☐ Applicant claims small entity status.
2. ☐ Check Enclosed. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

**FEE CALCULATION**

1. ☐ BASIC FILING FEE Subtotal (1) \$ \_\_\_\_\_  
(Type: \_\_\_\_\_)
2. ☐ EXTRA CLAIM FEES Subtotal (2) \$ \_\_\_\_\_
- Total Claims \_\_\_\_\_  
Independent Claims \_\_\_\_\_  
Multiple Dependent Claims \_\_\_\_\_
3. ☒ ADDITIONAL FEES Subtotal (3) \$ 180.00
- ☐ Surcharge - late filing fee or oath  
☐ Surcharge - late provisional filing fee or cover sheet  
☐ Extension for reply within \_\_\_\_\_ month  
☐ Notice of Appeal  
☐ Filing a Brief in Support of an appeal  
☐ Request for ex parte Reexamination  
☐ Petitions to the Commissioner  
☒ Submission of Information Disclosure Statement  
☐ Recording each patent assignment per property  
☐ Request for Continued Examination  
☐ Other: \_\_\_\_\_

**TOTAL AMOUNT OF PAYMENT** \$ 180.00

  
Kathryn J. Doty, Reg. No. 40,593  
January 21, 2004  
Date

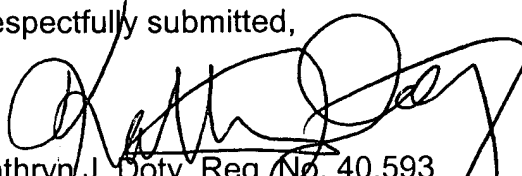
KJD/msc  
\*Enclosure

Transmitted via Facsimile No. (703) 872-9306 and  
Express Mail Label No. EV 324379158 US (Box 1 of 1)

PHA 2012.1 (3167/4Z/US)  
PATENT

A check in the amount of \$180.00 is enclosed to cover the fee specified in 37 CFR §1.17(p) for submission of this Supplemental Information Disclosure Statement.

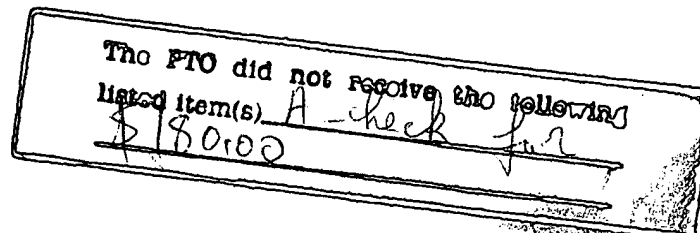
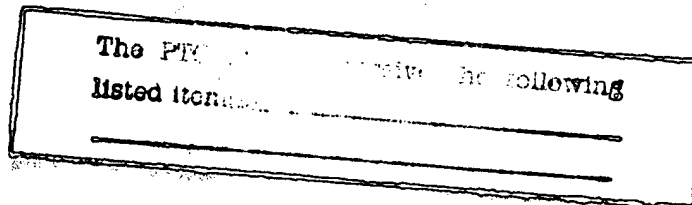
Respectfully submitted,



Kathryn J. Doty, Reg. No. 40,593  
SENNIGER, POWERS, LEAVITT & ROEDEL  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

KJD/msc  
\*Enclosures

Via Facsimile No. (703) 872-9306 and  
Express Mail Label No. EV 324379158 US (Box 1 of 1)



PTO/SB/08A JAN 21 2004 <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/857,873
				Filing Date	October 5, 2001
				Confirmation Number	2817
				First Named Inventor	John P. McKearn et al.
				Group Art Unit	1614
Examiner Name	Rebecca Cook				
Sheet	1	of	3	Attorney Docket No.	PHA 2012.1 (3167/4Z/US)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	172.	6,077,850		Carter et al.	06-20-2000
	173.	6,087,392		Reiter	07-11-2000
	174.	6,110,964		Robinson	08-29-2000
	175.	6,114,361		Robinson et al.	09-05-2000
	176.	6,156,798		Reiter	12-05-2000
	177.	6,214,870	B1	McClure et al.	04-10-2001
	178.	6,277,878	B1	Nakao et al.	08-21-2001
	179.	6,294,558	B1	Ando et al.	09-25-2001
	180.	6,303,628	B1	Nakao et al.	10-16-2001

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	181.	EP	1 081 137	A1	Pfizer Products Inc.	03-07-2001	
	182.	EP	1 088 550	A1	Pfizer Products Inc.	04-04-2001	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A JAN 21 2004 <b>SUPPLEMENTAL          INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/857,873
				Filing Date	October 5, 2001
				Confirmation Number	2817
				First Named Inventor	John P. McKearn et al.
				Group Art Unit	1614
Examiner Name	Rebecca Cook				
Sheet	2	of	3	Attorney Docket No.	PHA 2012.1 (3167/4Z/US)

	183.	EP	1 104 759	A1	Pfizer Products Inc.	06-06-2001	
	184.	EP	1 104 760	A1	Pfizer Products Inc.	06-06-2001	
	185.	EP	1 134 215	A1	Pfizer Products Inc.	09-19-2001	
	186.	EP	1 138 680	A1	Pfizer Products Inc.	10-04-2001	
	187.	WO	97/20824	A1	Agouron Pharmaceuticals, Inc.	06-12-1997	
	188.	WO	98/03516	A1	Pfizer Inc.	01-29-1998	
	189.	WO	98/30566	A1	Pfizer Inc.	07-16-1998	
	190.	WO	98/47890	A1	G.D. Searle & Co.	10-29-1998	
	191.	WO	00/09485	A1	Pfizer Products Inc.	02-24-2000	
	192.	WO	00/09492	A1	Pfizer Products Inc.	02-24-2000	
	193.	WO	00/73294	A2	Pfizer Products Inc.	12-07-2000	
	194.	WO	01/12611	A1	Pfizer Products Inc.	02-22-2001	
	195.	WO	01/40216	A1	Pfizer Products Inc.	06-07-2001	

### OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	196.	CRANE, C.H., M.D., et al., Initial Experience Combining Cyclooxygenase-2 Inhibition with Chemoradiation for Locally Advanced Pancreatic Cancer, Am. J. Clin. Oncol. (CCT), 2003, pp. S81-S84, Vol. 26, No. 4, Suppl. No. 2	
	197.	LIN, E., M.D., et al., Effect of Celecoxib on Capecitabine-Induced Hand-Foot Syndrome and Antitumor Activity, Oncology, Dec. 2002, pp. 31-37, Vol. 16, No. 12, Suppl.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A JAN 21 2004 <b>SUPPLEMENTAL  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/857,873
				Filing Date	October 5, 2001
				Confirmation Number	2817
				First Named Inventor	John P. McKearn et al.
				Group Art Unit	1614
				Examiner Name	Rebecca Cook
Sheet	3	of	3	Attorney Docket No.	PHA 2012.1 (3167/4Z/US)

	198.	SMITH, S.E., et al., Preliminary report of a phase II trial of gemcitabine combined with celecoxib for advanced pancreatic cancer, Proc. Am. Soc. Clin. Oncol., 2003, p. 374 (abstr 1502), Vol. 22	A
--	------	--	---

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.